K083281

FEB 25 2009

510(k) SUMMARY
ConMed Linvatec EL LightWave® Suction Ablator

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number _____.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Lisa Anderson
Regulatory Affairs Specialist
(727) 399-5501 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	ConMed Linvatec LightWave® Ablators
Common Name:	Electrode
Classification Name:	General & Plastic Surgery, 878.4400
Proposed Class/Device:	Class II
Product Code:	GEI

D. Predicate/Legally Marketed Devices

ConMed Linvatec LightWave® Integrated Electrode Ablator and LightWave® Integrated Electrode Suction Ablator	510(k) # K050923
ArthroCare® ArthroWands®	510(k) # K082323

E. Device Description

The *ConMed Linvatec LightWave® Ablators* are comprised of a range of non-suction and suction devices, operable by hand or foot control. The devices

consist of an electrical, insulation-coated electrode and ceramic insulator attached to an integrated handle and cord set, allowing attachment to commonly available electrosurgical generators.

F. Intended Use

The ConMed Linvatec Lightwave® Ablators are intended to be used for electrosurgical cutting and coagulation in arthroscopic procedures, using a conductive fluid environment. Additionally, the suction/aspiration versions of these devices have the capability for suctioning irrigation fluids.

Electrosurgical cutting and coagulation may be performed in various joints such as the shoulder, ankle, wrist, elbow, knee, and hip.

G. Substantial Equivalence

The ConMed Linvatec LightWave® Ablators are substantially equivalent in intended use and design to the legally marketed predicate devices LightWave® Integrated Electrode Ablator and LightWave® Integrated Electrode Suction Ablator (ConMed Linvatec) and the ArthroWands (ArthroCare). Performance testing has demonstrated the devices conform to applicable sections of ANSI/AAMI HF18:2001 and IEC 60601-2-2:2006 and do not raise any concerns with safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Linvatec
% Ms. Lisa Anderson
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

FEB 2 5 2009

Re: K083281
Trade/Device Name: ConMed Linvatec LightWave® Ablators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 6, 2009
Received: January 8, 2009

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K083281

Device Name: *ConMed Linvatec LightWave® Ablators*

Indications for Use:

The ConMed Linvatec Lightwave® Ablators are intended to be used for electrosurgical cutting and coagulation in arthroscopic procedures, using a conductive fluid environment. Additionally, the suction/aspiration versions of these devices have the capability for suctioning irrigation fluids.

Electrosurgical cutting and coagulation may be performed in various joints such as the shoulder, ankle, wrist, elbow, knee, and hip.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083281